

Attorney Docket No.: P-633 (TI-0020)
Inventors: Taylor and Yu
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REMARKS

Claims 13-16 are pending in the instant application. Claims 13-16 have been rejected. Claims 13 and 15 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejections under 35 U.S.C § 112, Second Paragraph

Claims 13-16 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, claim 13 has been rejected for reciting "a system for computer implemented adjustment to generate values useful for grouping." The Examiner suggests that it is unclear what limitation the grouping imparts to the system. The Examiner has requested clarification. Applicants respectfully disagree with this rejection. However, in an earnest effort to facilitate the prosecution of this application, Applicants have amended claim 13, removing the phrase "to generate values useful for grouping the plurality of chromatographic elution profiles". In light of this amendment, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 13 has also been suggested to be unclear in reciting "a computer having a processor and a memory, wherein the processor plots sets of data from a plurality of chromatographic elutions...wherein each set of data is obtained from a separation of a DNA mixture". The Examiner suggests that these

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appear to be method steps, and therefore it is unclear what limitation of the system this step is intended to provide. The Examiner has requested clarification. Applicants respectfully disagree with this rejection. However, in an earnest effort to clarify the present invention, Applicants have amended claim 13 to indicate that the processor comprises instructions for carrying out the claimed steps. In light of this clarification, it is respectfully requested that this rejection be reconsidered and withdrawn.

Claim 13 is further suggested to be unclear in reciting "for comparison with values from control profiles to detect mutations in the sample DNA". The Examiner requests clarification as to what limitation of the system is intended by this step. Applicants respectfully disagree with this rejection. However, in an earnest effort to facilitate the prosecution of this application, Applicants have amended claim 13, removing the phrase "for comparison with values from control profiles to detect mutations in the sample DNA". In light of this amendment, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 15 is suggested to be unclear in reciting "the system of claim 13 wherein said processor further comprises the steps of". The Examiner requests clarification as to whether Applicants intend that the processor comprises instructions for performing steps or some other limitation. In an earnest effort to clarify the claimed invention, Applicants have amended claim 15 to indicate that the processor comprises instructions for performing the claimed steps. In light of this clarification, it

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is respectfully requested that this rejection be reconsidered and withdrawn.

II. Rejections under 35 U.S.C. §103

Claims 13-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hunt (Quantitative Pattern Recognition Using Nonlinear Model-based Analysis. A Dissertation presented for PhD at The University of Tennessee, May 1998). The Examiner suggests that Hunt teaches the analysis between observed time series patterns and physical phenomenon of interest in using pattern recognition and signal processing theory (page 5, lines 13-16). It is suggested that Hunt teaches baseline estimation of chromatographic data applied to several chromatographs (page 107, section 8.2), wherein baseline estimations are made by a fitting function to determine minimum and maximum signal. Hunt is suggested to teach peak modeling (page 110, section 8.3) in which estimates of peak model parameters are made by analyzing time series information, wherein once peaks are located, the first peak amplitude above baseline is obtained and further modeling is performed using least squares analysis to generate a peak center (page 113, section 8.3.2). It is suggested that the sliding window approach is used to fit multiple peaks across a time series using least squares minimization (page 147, line 19-20). The Examiner suggests that Hunt teaches a scale from 0 to 1, based upon magnitude of the peak, as in claim 14 (page 14, Figure 8.3). It is acknowledged that Hunt does not teach or suggest MIFPC, however, it would have been *prima facie* obvious at the time the invention was made to use the system of Hunt to

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adjust signal and time data of MIPC profiles as Hunt states that the fundamental components to any peak detection and measurement operation involves the accurate estimate of a baseline (page 16, section 1.4.5) and peak adjustment (page 17, section 1.4.6). Applicants respectfully traverse this rejection.

MPEP 2142 indicates that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicants' invention is a processor which contains instructions for plotting chromatographic data to create profiles, selecting first and second time points defining a time span for each profile, and adjusting the baseline of each profile by applying a slope factor to each detector response value, said slope factor derived from a line connecting the detector response values at said first and second time points such that all of the profiles have a common baseline. As such, said slope factor describes a linear relationship between the first and second time points. This is illustrated at the passage between page 29 (line 17) and page 30 (line 4) which teaches that the y-values at the first and second time points are set to the same value to, e.g., give a baseline slope of zero. In contrast, Hunt teaches estimating chromatographic parameters to

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generate a model of chromatographic peaks, wherein baseline estimations are carried out using high order polynomials such as third order (page 76) or fifth order polynomials (page 107) to fit a set of data points to a curve. Hunt teaches that the disclosed analysis is a nonlinear model-based approach to quantitatively analyze time series data generated by analytical instruments (page vi, first two lines of the abstract). Therefore, in addition to failing to teach or suggest baseline adjustment by applying a slope factor derived from a line connecting the detector response values at said first and second time points, Hunt also fails to provide the motivation to modify the teachings therein to arrive at the instant invention because Hunt teaches that his approach is nonlinear, and linear approaches are less suitable for analyzing time series data (see the paragraph bridging pages 16 and 17). Accordingly, because Hunt fails to provide the necessary teachings, suggestion or motivation, Hunt fails to make obvious the instant invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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